Overview of Kidney Dialysis Studies

And Providers of End Stage Renal Disease Care

By the Staff of
The Florida House of Representatives
Committee on Health Regulation
The Honorable Frank Farkas, D.C., Chair
The Honorable Eleanor Sobel, Vice Chair
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INTRODUCTION

This report is the final product of an intensive review by staff of the Committee on Health Regulation of two studies submitted to the Legislature in 1999 and 2000 relating to the delivery of End Stage Renal Disease (ESRD) services. This report also examines the need for exemptions granted to certain clinical laboratories and nephrologists pursuant to s. 456.053, F.S., "The Patient Self-Referral Act."

The impetus of this interim report is to clarify the multiple issues surrounding the delivery of end stage renal disease services to patients in Florida and to determine if the state is at a financial risk due to fraud or abuse within the Medicaid system. Other areas of expressed concern stem from allegations that the three major companies (providers) control the market in the end stage renal disease industry, creating a monopoly, thereby, eliminating competition and resulting in an increased price for service.

The purpose of this study and the methodology used to prepare this report was to conduct an objective review of the conclusions drawn from the published reports by the Agency for Health Care Administration (AHCA) and the University of South Florida (USF) and to determine the need, if any, for additional legislative action. The two mandated studies relate to:

- Clinical laboratory services for kidney dialysis patients in Florida;
- Utilization rates of clinical laboratory services for dialysis patients;
- Financial arrangements among kidney dialysis centers, their medical directors, referring physicians, any business relationships and affiliations of laboratory services;
- Any self-referral to clinical laboratories; and
- Quality and effectiveness of kidney dialysis treatment in Florida.

Additionally, this report analyzes current remedies for fraud and abuse in health care; existing state and federal regulation of ESRD Providers; the Department of Justice's action against ESRD providers in Florida and the subsequent settlement agreements; the Patient Self-Referral Act of 1992; and the Federal Stark Amendment as it relates to end stage renal disease.

End stage renal disease care is provided in both an inpatient and outpatient setting. The focus on this interim report provides an examination of the relationship of the providers in the outpatient setting exclusively. Among these providers, there are primarily four major companies providing services in Florida:

- *ESRD Laboratories*, an independent lab located in Broward County;

- *Fresenius,* a German-owned company with US headquarters in Lexington, Massachusetts, providing both clinical dialysis services and laboratory services (vertically integrated);

- *Gambro Healthcare, Inc.,* a Swedish-owned company providing both dialysis services and laboratory services with the laboratory headquartered in Broward County, Florida (vertically integrated); and

- *DaVita, Inc*., a.k.a. *Total Renal Laboratories,* a company providing both dialysis services and laboratory services, with the laboratory located in Deland, Florida (vertically integrated).

There are differing opinions regarding whether vertically integrated corporations should be allowed to operate in Florida or whether there should be a divestiture of one service from the other within a single corporate entity. However, it is important to note that when a patient receives dialysis treatment in an inpatient setting, e.g., in a local hospital, it is customary and permissible for the hospital to provide both the dialysis service and the laboratory service. Lack of action on the part of the Legislature to prevent or prohibit outpatient dialysis clinics operating in tandem with their corresponding laboratories, makes it permissible.

Representatives of ESRD Laboratories in Fort Lauderdale met with staff of the Committee on Health Regulation and expressed the following concerns:

- Three major companies control the market in the end stage renal disease industry, creating a monopoly, thereby, eliminating competition and resulting in an increased price for service.

- They argued that there is over utilization of services to patients, resulting in higher Medicaid cost to the state, citing potential fraud and abuse of the Medicaid system.

In addition to an evaluation of the aforementioned concerns, this report provides findings, conclusions, and recommendations of the following issues:

1. Deficiencies of the 1999 and 2000 studies;
2. Patient Self-Referral Act;
3. Fraud and Abuse;
4. Antitrust Violations; and
5. Feasibility of Divestiture of Clinical Laboratory and Clinical Laboratory Services.

EXECUTIVE SUMMARY

The impetus of this interim report is to clarify the multiple issues surrounding the delivery of end stage renal disease services to patients in Florida and to determine if the state is at a financial risk due to fraud or abuse within the Medicaid system. Other areas of expressed concern stem from allegations that the three major companies (providers) control the market in the end stage renal disease industry, creating a monopoly, thereby, eliminating competition and resulting in an increased price for service.

The focus of this study was a review of the:

- Published reports from the Agency for Health Care Administration (AHCA) and the University of South Florida (USF);
- ESRD industry in the State of Florida as it exists;
- Current remedies for fraud and abuse in health care;
- Existing state and federal regulation of ESRD Providers;
- Department of Justice action against ESRD providers in Florida and the subsequent settlement agreements;
- Patient Self-Referral Act of 1992; and
- Federal Stark Amendment as it relates to end stage renal disease.

The outcome of this report is an objective review of the conclusions drawn from each study and a determination of need, if any, for additional legislative action.

End stage renal disease is a chronic, life-threatening condition that affects the kidneys, heart, and other vital organs, if appropriate treatment is not received. Healthy kidneys clean blood in the human body by removing excess fluid, minerals, and wastes. Kidneys also make hormones that keep bones strong and blood healthy. When an individual experiences kidney failure, harmful wastes build up in the body, the blood pressure may rise, and the body may retain excess fluid and not make enough red blood cells. When this occurs, it is necessary in order to sustain life to artificially replace the work of failed kidneys.

Hemodialysis cleans and filters blood using a machine to temporarily rid the body of harmful wastes, extra salt, and extra water. Hemodialysis helps control blood pressure and helps the body keep the proper balance of chemicals such as potassium, sodium, calcium, and bicarbonate.

Hemodialysis is usually needed three times a week. Each treatment lasts from 3 to 5 or more hours. If a patient chooses hemodialysis as a treatment, several months before the first treatment, an access to the bloodstream will need to be created. Some patients may need to stay overnight in the hospital, but many patients have their access placed on an outpatient basis. This access provides an efficient way for blood to be carried from the body to the dialysis machine and back without causing discomfort. The two main types of access are a *fistula* and

a *graft.* When the disease progresses more quickly, sometimes a catheter is used.

To see whether dialysis is removing enough urea, the clinic periodically, normally once a month or once a week, tests a patient's blood to measure dialysis adequacy. Blood is sampled at the start of dialysis and at the end. The levels of urea in the two blood samples are then compared.

The Agency for Health Care Administration licenses the clinics in which treatment is provided and administers the Medicaid funds that are available to pay for the services.

Staff has reviewed and analyzed the kidney dialysis studies conducted in 1999 and 2000 and identified the deficiencies of those studies, determined the impact of repealing exemptions contained in the Patient Self-Referral Act of 1992, investigated the claims of fraud and abuse in the Medicaid industry, studied provisions relating to Antitrust violations, and examined the feasibility of divestiture of services, and have concluded the following:

- ✓ **Deficiencies of the 1999 and 2000 Studies–** In evaluating the studies conducted by the AHCA and the USF, staff concludes that the USF Study draws conclusions based upon "potential opportunities for fraud and abuse" without a discussion of existing remedies in place to prevent fraud and abuse. Such existing remedies or controls in the system that minimize and prevent abuse, include, but are not limited to:

    - State regulations:

        - Medicaid Provider Contracts;
        - Medicaid Reimbursement Methodology;
        - Medicaid Program Integrity;
        - Disease Management Organization; and
        - Clinical Licensing/ACHA licenses all laboratories and acts as the certifying agency for the federal Clinical Laboratory Improvement Amendment (CLIA) Certification.

    - Federal regulations:

        - Medicare Provider Contracts;
        - Medicare & Medicaid Program Integrity Unit; and
        - Network 7

    - Federal regulatory and enforcement agencies, which agencies enforce existing state and federal anti-kickback and self-referral laws;

- Pre-payment and post-payment reviews by CMS carriers and other third party payors; and

- The existence of corporate integrity agreements between some of the dialysis companies and the federal government, which agreements have similar provisions as the companies' voluntary compliance programs.

Moreover, the Dialysis Study failed to report that the dialysis companies have cooperated with the federal government to resolve historic issues and have maintained their standing as Medicare providers.

While the federal government is the primary payor of health services of patients with ESRD, the USF report failed to recognize or discuss that all ESRD providers are also Florida Medicaid Providers with underlying contractual regulations.

There are four major ESRD clinical laboratories providing services to dialysis patients in Florida. However, the USF Study limited the scope of its review to only three of the four clinical laboratories: Fresenius Medical Care; DaVita Inc.; and Gambro Healthcare, Inc. If information had been requested and received from ESRD Laboratories, the only Florida-based clinical laboratory, it would have provided an important control group for analysis of test utilization data, as ESRD Laboratories is a non-vertically integrated clinical laboratory.

✓ **Patient Self-Referral Act of 1992 -** When the Patient-Self Referral Act was statutorily created in 1992, most nephrologists treated their patients with end stage renal disease on an outpatient basis in an independent clinic that was typically owned by the nephrologist. The Act, as set forth in s. 456.053, F.S., governs physician practice and within the confines of this report, speaks to either a nephrologist or a pathologist. When a violation occurs within s. 456.053, F.S., the violation is prosecuted by ACHA through the disciplinary panel of the Board of Medicine. If the exemptions in ss. 456.053(3)(o)3.h. and 456.053(3)(o)3.l., F.S., were to be repealed and it becomes illegal for a nephrologist to refer his patients to a clinic in which he has a financial interest, and he is subsequently prosecuted to the fullest extent by the Board of Medicine, the physician's license would possibly be suspended and he could face fines and penalties up to $100,000.

Removing qualified physicians from practicing medicine, will not address the concerns raised---which are primarily increased competition among corporations, prevent over-utilization, and promote better patient care. However, <u>if a practicing nephrologist is prohibited from referring a patient to a facility for whom he is employed</u>, such as the relationship that currently exist when the physician is the medical director of an outpatient clinic or hospital, <u>it may impede the dialysis clinic from employing a physician from their local</u>

community for service. As well, it may require the dialysis clinic to employ a physician that is not treating patients as the medical director of the facility.

- ✓ **Fraud and Abuse -** Both the Medicare and Medicaid programs are highly regulated by the state and federal governments as demonstrated in this report. In the event there is fraud and abuse within a practicing facility, there are clear and defined remedies to investigate, fine and prosecute such abuse as demonstrated by the Operation Restore Trust Project by the federal government's office of Program Integrity for Medicare and Medicaid.

  In 1995, the Legislature amended s. 409.905, F.S., Mandatory Medicaid Services, to include the treatment for ESRD services. According to AHCA, there are about 400+ Medicaid funded Florida ESRD patients out of approximately 17,000+ total ESRD patients in Florida. In fiscal year 1999-2000, Florida spent approximately $113,000,000 in Medicaid dollars to treat patients diagnosed with end stage renal disease. The $113,000,000 represents all costs associated with treatment, hospitalization, transportation, clinical laboratory charges and pharmaceuticals. Of that amount, only $4-5 million was spent on actual charges for clinical dialysis services and laboratory cost.

  Enforcing the regulations that exist through ACHA is a clearer and more definitive avenue to address any concerns of fraud and abuse than creating additional programs or government authority as recommended in the USF Report.

- ✓ **Antitrust Violations -** In the event it is suspected that a monopoly exists within the health care industry, there are clear and definitive remedies under the Attorney General's office through the enforcement of the antitrust statutes. When the Attorney General's office investigates an industry for a monopoly and there is found no cause for concern, no legal action is taken and therefore this information is considered confidential and is not publicly disclosed. If such an investigation has occurred within Florida, the Attorney General's office is not at liberty to disclose such an investigation. However, through the no-action antitrust statues, an industry may ask the Attorney General's office to issue an opinion as to whether a monopoly exists, which is made public.

- ✓ **Feasibility of divestiture of clinical laboratory and clinical dialysis services** - Currently, clinical dialysis facilities operate in tandem with their corresponding laboratory. A patient that is treated in a Gambro, Fresenius or DaVita clinic has the blood work sent directly from the clinic to the laboratory. All patient registration/financial information and medical records are obtained on the clinical side. In order to bill for laboratory work done on the patient specimen, the laboratory is dependent on the clinic to provide all patient financial information.

> The selection of the use of a laboratory, absent any third party payor restrictions, has historically been at the discretion of the physician or facility providing the service. The decision is based on the reliability of service that the lab provides, and this decision is considered an important decision-making process in overall patient care. Only when there is substantial risk to patient care should the state intervene in making medical decisions concerning the delivery of patient care. The divestiture of such services, absent any direct risk to patient care, is not recommended.

In conclusion, there is convincing evidence that mechanisms are already in place to address allegations of fraud and abuse in the Medicaid industry without creating additional programs or government authority. Additionally, regulations already exist to address concerns of Antitrust violations. Further, it is concluded that repealing the nephrologist's exemptions in the Patient Self-Referral Act will not increase competition or provide opportunities for competition, but instead would eliminate provisions that are obsolete in today's renal dialysis market.

It is therefore recommended that no legislative action is needed to address the concerns regarding monopoly, over-utilization of services to patients with ESRD, or the divestiture of vertically integrated services within the ESRD industry.

Additionally, it is recommended that through the Florida Health Care Community Antitrust Guidance Act, codified at s. 408.18, F.S., under the investigation of the Attorney General's office that one or all four major corporations seek guidance from the Attorney General's office for a public determination as to whether a monopoly exists in the dialysis industry.

METHODOLOGY

On July 13, 2001, Speaker Tom Feeney approved the proposal from the Committee on Health Regulation to re-examine the studies for Kidney Dialysis by the Agency for Health Care Administration (AHCA) and the Florida Health Information Center, College of Public Health, University of South Florida (USF). Chair Frank Farkas, D.C., sent a letter of engagement to Ms. Laura Branker, Acting Secretary at AHCA on July 23, 2001, notifying AHCA of the pending interim study. Subsequently, staff of the Health Regulation Committee conducted informal interviews; reviewed existing reports and journal articles, reviewed federal and state laws, developed and disseminated questionnaires, made site visits to dialysis clinics and laboratories, analyzed existing data, and requested follow-up information for clarification.

The review of published documents consisted of the following:

- **Reports:**

  2001 Florida Dialysis Study, by the Agency for Health Care Administration and the Florida Health Information Center, College of Public Health, University of South Florida.

  DRAFT of the Laboratory Services for Dialysis Patients in Florida: A Report to the Florida Legislature, December 1999, by the Agency for Health Care Administration.

  Final Report of Laboratory Services For Dialysis Patients in Florida: A Report to the Florida Legislature, February 1, 2000, by the Agency for Health Care Administration.

  The Florida Senate Interim Project Report 2001-044, *Public Records Exemption – Health Care Provider Information For Antitrust Review,* by the Senate Committee on Health, Aging and Long-Term Care.

  OPPAGA Justification Review Report No. 01-27, *Medicaid Disease Management Initiative Sluggish, Cost Savings Not Determined, Design Changes Needed, May 2001,* by the Office of Program Policy Analysis and Government Accountability, an office of the Florida Legislature.

  OPPAGA Justification Review Report No. 01-39, *Medicaid Program Integrity Efforts Recover Minimal Dollars, Sanctions Rarely Imposed, Stronger Accountability Needed, September 2001,* by the Office of Program Policy Analysis and Government Accountability, an Office of the Florida Legislature.

  The Florida House of Representatives Interim Report, Relationship between Dermatologists, Health Maintenance Organizations, and Clinical Laboratories,

December 1999, by the Staff of the Committee on Health Care Licensing & Regulation.

Health Outcomes Series: Complications of Diabetes Study, 1999 Report, Agency for Health Care Administration State Center for Health Statistic.

Historical Policy Briefing, Health Care and Welfare, The Florida House of Representatives August 2000.

- **Journals:**

Dialysis & Transplantation *Lack of Oversight and Accountability in the Medicare ESRD Program, September 2000.*

The New England Journal of Medicine, Vol. 341, No. 22, *Quality and Equity in Dialysis and Renal Transplantation,* November 25, 1999.

The New England Journal of Medicine, Vol. 341, No. 22, *Effect of the Ownership of Dialysis Facilities on Patient's Survival and Referral for Transplantation,* November 25, 1999.

- **Industries Policy and Procedures:**

Inspector General, Office of Health Care Financing Administration, Medical Fraud Alert, *Arrangements for the Provision of the Clinical Lab Services, 1995.*

Certification of facilities that provide ESRD: http://www.gpo.gov/nara/cfr/cfr-retrieve.html - page1

Medicare Manuals: www.hcfa.gov/pubforms/p2192toc.htm

Medicare cap on lab test fee payments:www.hcfa.gov/audience/planprov.htm

- **Review of Media:**

CNN Financial News Network, *Disease Management Popular Among HMOs Control of Chronic Illness May Save Millions in Long-run,* August 9, 2001.

Yahoo Finance, *Total Renal Unit is Target of Medicare Probe,* August 4, 1998.

Yahoo Finance, *Gambro Reaches Settlement on US Laboratory Services*, July 13, 2000.

Netscape Business Journal, *US Government Agency Makes Overpayment Determination for Laboratory Services, October 20, 1999.*

Modern Healthcare, *Mich. Attorney General Sues Gambro, Dialysis Firm Accused of monopolizing market in western Mich. after acquisition spree*.

Michigan Office of Attorney General, Press Release, *Attorney General, Company Settles Dialysis Dispute, Gambro agrees to sell 3 clinics. Move to spur competition in 3 areas.*

Bloomberg.com, *Fresenius Medical Unit Paid Kickbacks, Suit Claims,* February 10, 2000.

Various press releases from:
www.Gambro.com
www.Freseneius.com
www.esrdnetworks.org
www.kidneyfla.org

- **Statutory Review:**

Chapter 99-356, Laws of Florida
Chapter 2000-318, Laws of Florida
Chapter 2001-253, Laws of Florida, General Appropriations Act of 2001
Section 408.18, F.S., Florida Health Care Community Antitrust Guidance Act
Section 409.906, F.S., Optional Medicaid Services, Dialysis Facility Service
Section 409.908, F.S., Reimbursement of Medicaid Providers
Section 409.912, F.S., Cost-effective Purchasing of Health Care
Section 409.913, F.S., Oversight of the Integrity of the Medicaid Program
Section 456.053, F.S., Patient Self-Referral Act of 1992
Section 483.245, F.S., Rebates Prohibited
Chapter 542, F.S., The Florida Antitrust Act of 1980

United States Code, Title 42, section 1395nn, Limitation on Certain Physician Referrals

United States Code, Title 42, section 411.350, Physician ownership of and Referral of Patients or Laboratory Specimens to Entities Furnishing Clinical Laboratory or Other Health Services

Federal Register/Vol.57, No.48, Health Care Financing Administration, Medicare program; Physician Ownership of, and Referrals to Health Care Entities that Furnish Clinical Laboratory Services

Federal Register/Vol. 60, No. 156, Health Care Financing Administration, Medicare Program; Physician Financial Relationship with, and Referrals to,

Health Care Entities That Furnish Clinical Laboratory Services; Financial Relationship Reporting Requirements; Final Rule

- **Analysis of Existing Data Included:**

  Review of data submitted by RMS Disease Management Inc., to the Agency for Health Care Administration.

  Review of Medicaid Provider's Freestanding Dialysis Center Services, Coverage and Limitations Handbook.

  Review of Medicaid Provider's Independent Laboratory, Coverage and Limitations Handbook.

Questionnaires were prepared and sent to the Agency for Health Care Administration and the Centers for Medicare and Medicaid's [formerly known as Health Care Financing Administration (HCFA)] regional office in Atlanta.

Interviews were conducted with representatives from AHCA, attorneys from Gambro Health Care, former attorney representing Fresenius vs. Federal Government, Dr. Mark Ginsburg, owner of ESRD Laboratory in Fort Lauderdale, Lobbyist representing ESRD Labs in Fort Lauderdale, Lobbyist representing Gambro, the Medical Directors of a Gambro Dialysis Clinic and Laboratory, and the Executive Director for the Florida Kidney Foundation.

Site visits were conducted by House staff to a Gambro clinical dialysis center in Tallahassee and the ESRD Lab and Gambro Laboratories in Fort Lauderdale.

PRESENT SITUATION AND BACKGROUND INFORMATION

Legislative History

Because of allegations of over utilization of services resulting in fraud and abuse of the Medicaid system and the claim of a monopoly in the end stage renal disease industry, the 1999 Legislature, pursuant to Chapter 99-356, Section 4, Laws of Florida, and Chapter 99-397, Section 187, Laws of Florida, required the Agency for Health Care Administration (AHCA), in conjunction with other agencies as appropriate to:

> "…conduct a detailed study and analysis of clinical laboratory services for kidney dialysis patients in the State of Florida. The study shall include, but not be limited to, an analysis of the past and present utilization rates of clinical laboratory services for dialysis patients, financial arrangements among kidney dialysis centers, their medical directors, any business relationships and affiliations of clinical laboratory services for dialysis patients in Florida; and the average annual revenue for dialysis patients for clinical laboratory services for the past 10 years."

The Agency was directed to report its findings to the Legislature by February 1, 2000. Subsequently, the agency issued the report, which concluded that additional time and investigative resources were necessary to adequately respond to the legislative directives. Therefore, during the 2000 Legislature,

> "…the sum of $230,000 from the Agency for Health Care Administration Tobacco Settlement Trust Fund is appropriated to the Agency for Health Care Administration to contract with the University of South Florida to conduct a review of laboratory test utilization, any self-referral to clinical laboratories, financial arrangements among kidney dialysis centers, their medical directors, referring physicians, and any business relationships and affiliations with clinical laboratories, and the quality and effectiveness of kidney dialysis treatment in this state."[1]

The USF 2000 Study concluded that:

> "Pursuant to our study and the AHCA Dialysis Report, the proprietary nature of the financial and contractual data required to ascertain the laboratory utilization rates and financial relationships, as requested by the Legislature, preclude a more detailed assessment than either effort achieved. Without mandatory reporting requirements, the Legislature's concerns cannot be completely and accurately addressed."

[1] Chapter 2000-318, Section19, Laws of Florida.

In addition, the USF 2000 Study recommended that:

> "While all of the Legislature's stated concerns could not be addressed due to lack of subpoena power and the absence of mandatory standardized reporting requirements for dialysis organizations, this study has provided important and useful insight into areas of potential fraud, abuse and kickbacks within Florida's dialysis industry…."

In July 2001, Speaker Feeney directed the Committee on Health Regulation to re-examine the 1999 and 200 studies and provide a determination of need for any additional legislative action.

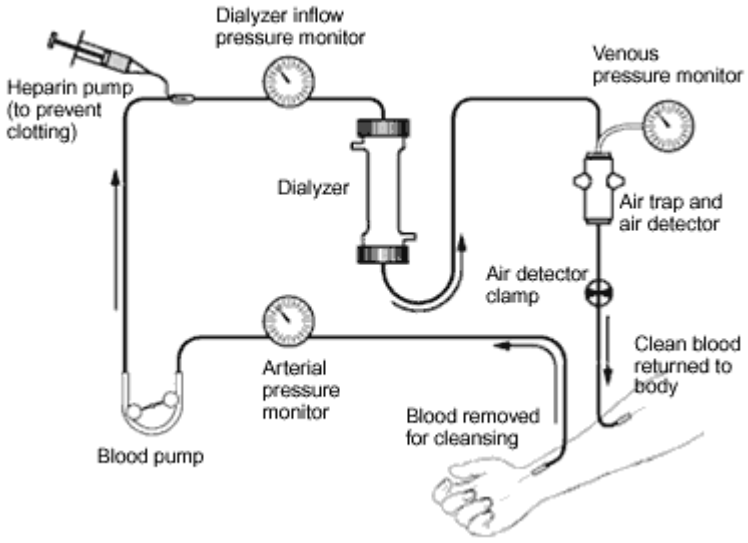
End Stage Renal Disease/Hemodialysis

Healthy kidneys clean blood in the human body by removing excess fluid, minerals, and wastes. Kidneys also make hormones that keep bones strong and blood healthy. When an individual experiences kidney failure, harmful wastes build up in the body, the blood pressure may rise, and the body may retain excess fluid and not make enough red blood cells. When this occurs, it is necessary in order to sustain life to artificially replace the work of failed kidneys.

There are limited numbers of treatments available to patients with end stage renal disease: hemodialysis; peritoneal dialysis; and kidney transplantation. Each has advantages and disadvantages. For purposes of this study, the hemodialysis procedure will be presented.

Hemodialysis cleans and filters blood using a machine to temporarily rid the body of harmful wastes, extra salt, and extra water. Hemodialysis helps control blood pressure and helps the body keep the proper balance of chemicals such as potassium, sodium, calcium, and bicarbonate.

Hemodialysis uses a filter called a dialyzer that functions as an artificial kidney to clean blood. During treatment, blood travels from the body through tubes into the dialyzer, which filters out wastes and extra water. Then the cleaned blood flows through another set of tubes back into the body. The dialyzer is connected to a machine that monitors blood flow and removes wastes from the blood.



Source: National Kidney Foundation

Hemodialysis is usually needed three times a week. Each treatment lasts from 3 to 5 or more hours. During treatment, patients typically read, write, sleep, talk, and watch TV.

To see whether dialysis is removing enough urea, the clinic periodically, normally once a month or once a week, tests a patient's blood to measure dialysis adequacy. Blood is sampled at the start of dialysis and at the end. The levels of urea in the two blood samples are then compared. Two methods are generally used to assess dialysis adequacy, URR and Kt/V.

If a patient chooses hemodialysis as a treatment, several months before the first treatment, an access to the bloodstream will need to be created. Some patients may need to stay overnight in the hospital, but many patients have their access placed on an outpatient basis. This access provides an efficient way for blood to be carried from the body to the dialysis machine and back without causing discomfort. The two main types of access are a *fistula* and a *graft.* When the disease progresses more quickly, sometimes a catheter is used.

There are possible complications from dialysis, which may result in hospitalization; vascular access problems are the most common reason. Other common problems include infection, blockage from clotting, and poor blood flow. These problems can keep treatments from working and as a result, patients may need to undergo repeated surgeries in order to get a properly functioning access.

Other problems can be caused by rapid changes in the body's water and chemical balance during treatment. Muscle cramps and hypotension, or a sudden drop in blood pressure, are two common side effects. Most patients need a few months to adjust to hemodialysis.

Hemodialysis and other dialyses are treatments that help replace the work of the kidneys. These treatments help the patient feel better and live longer, but they do not cure kidney failure. Although patients with kidney failure are now living longer than ever, over the years kidney disease can cause problems such as heart disease, bone disease, arthritis, nerve damage, infertility, and malnutrition. These problems are not cured with dialysis, but helped treated through the dialysis process.

End Stage Renal Disease Industry

Currently, vertically integrated corporate entities that have dialysis clinics also have clinical laboratories that perform laboratory procedures on dialysis patients concomitant to the dialysis services. For example, one of the leading providers of services for end stage renal disease care in Florida consists of several components:

- Gambro Healthcare Patients Services, Inc.: owns and operates renal dialysis clinics in twenty (20) states and the District of Columbia. As well, they provide managed care, clinical laboratory services, manufactures and distributes hemodialysis and acute dialysis products and equipment services.[2]

- Gambro Healthcare Laboratory Services, Inc.: is a subsidiary of Gambro Healthcare Patient Services, Inc., and provides clinical laboratory services to Gambro clinical facilities as well as to other independent clinics throughout the United States.

The federal government has investigated and brought charges against End Stage Renal Disease (ESRD) providers, specifically clinical laboratories, for allegations of filing false claims and other inappropriate billing practices. Fresenius and Gambro argue that the investigation and charges are a result of improper billing practices, not because they were billing for services that they did not provide. Both of these corporations have entered into a settlement agreement with the federal government, which included payments and the issuance of a Corporate Integrity Agreement. Among the providers that charges were brought against and settlements made, all providers have maintained their status as Certified Medicare Providers.

Under current law, a nephrologist, when referring for renal dialysis services and supplies, is included as one of a limited number of practitioners and services that are exempt from the prohibition against self-referral in s. 456.053, F.S., the "Patient Self-Referral Act of 1992." The same is the case for a health care provider for diagnostic clinical laboratory services where such services are directly related to renal dialysis. Such services are supposedly exempted

[2] United States, EX REL vs. Gambro Healthcare Patient Services, Inc., case number 3-98 0812.

because of the highly specialized nature of the services and the limited number of providers of such services.

Throughout the country and here in Florida, hemodialysis is usually done in a dialysis center by nurses and trained technicians, which is headed by a medical director and in most cases a practicing nephrologist. This treatment is provided at more than 270 dialysis facilities in Florida. While a majority of these facilities are owned collectively by three national health care providers (Gambro, Fresenius and DaVita), some facilities are owned, either in whole or in part, by physicians, hospitals and other non-profit companies.

According to information provided by Network 7, an oversight agency funded by the federal government, Florida's ESRD population represents approximately 15,733 patients requiring chronic, life-sustaining dialysis treatment. According to the Disease Management Organization in AHCA, about 3 - 4000 of these patients are insured by Medicaid, while the majority is insured by Medicare and the remaining patient population insured by private insurance. Last year, approximately 5,700 new cases of patients diagnosed with ESRD lived in Florida. There is a constant newly-diagnosed patient population for end stage renal disease; however, mortality and transplantation can reduce the number of patients actually being treated by hemodialysis.

Up to the early 90's, most nephrologists treated their patients with end stage renal disease on an outpatient basis in an independent clinic that was typically owned by the nephrologist. In the mid-90's the renal dialysis industry experienced a rapid consolidation by vertically integrated corporate entities. Corporate entities started purchasing the independent clinics and laboratories since, "Such vertically integration provides opportunities for important economies of scale and efficiencies…."[3] The consolidation in the dialysis industry tracks the consolidation movement taken in other sectors of the health care industry (hospitals and nursing homes) and is a function of similar "market driven" pressures, e.g., third party payor reimbursement, increased patient acuity and increased costs to provide care.

As in other segments of health care, benefits that consolidation has brought to the dialysis industry include: improved patient outcomes; collection and analysis of clinical and demographic data through electronic data networks; cost efficiencies and increased buying power in contracting favorable pricing with managed care payors; greater access to outpatient dialysis care; and comprehensive, continuous and coordinated care (disease state management).

Although consolidation brought efficiencies to patient care, corporate entities struggled to reconcile numerous billing systems of many smaller independent clinics under the direction of one system. This was done at a time when the federal government increased Medicare regulations. The unsuccessful attempt

[3] *2001 Florida Dialysis Study*, Agency for Health Care Administration, University of South Florida Report

to consolidate many systems may have contributed to faulty billing systems, which resulted in the federal investigations and subsequent settlement agreements.

While the corporate entities have gained control of the dialysis market, there still remains a need for the nephrologist. As the practicing nephrologists were bought-out of the independently owned clinics; subsequently, most were offered a medical director's position within the corporately owned clinic. The clinic's contractual arrangements as a Medicaid or Medicare provider with the state and federal government require that a renal dialysis clinic operate under the direction and supervision of a medical director and furthermore, require that this relationship exist on a "fee for services basis."

As presented in the USF Report, and mandated by state and federal law, the financial relationship that exist between the nephrologist and the dialysis clinic is a standard employee/employer relationship. This financial arrangement between the corporate dialysis entity and the medical director is similar to the same arrangement found in most hospitals. For example, a practicing physician from the community also acts as the medical director of the corporately owned facility. Such contractual arrangements are standard employee/employer relationships. The medical director is hired on a fee for service basis, at fair market value, and regardless of the number of patients treated in the clinic or the increase/decrease in annual revenues, the salary of the medical director is unchanged. There appears to be some caveats to this relationship, whereby, in some situations a medical director's enumeration is based on the center achieving established cost containment and quality care objectives.

A similar relationship exist in the Laboratory setting, whereas, the corporate owned laboratory is operated and supervised under the direction of a medical director, who typically is a pathologist. Some exceptions to this straightforward employee/employer relationship exist, whereby, the medical director maybe the property owner of the clinic or lab. This type of contractual arrangement is permissible under section 456.053(3)(k)3., F.S., and under the federal regulations, known as the Stark Amendment, as long as the tenet landlord relationship is based on fair market value.

As with most health services, sometimes the choice of a laboratory service is limited or dictated by the third party payor. With exception to the third party payor restrictions, most dialysis clinic's medical directors make an independent decision in its selection of a laboratory. Within the corporate settings of Gambro, Fresenius and DaVita, the medical directors are free to choose their laboratory of preference, absent any third party payor restrictions. Lab selection is usually based on the accuracy of reporting. "…The accuracy of the opinion issued by a clinical laboratory can be a life or death matter as documented by public testimony at the committee (House Committee on Health Care Licensing & Regulation) hearing on November 3, 1999. In addition, the Boston Globe article

dated December 1, 1999, cited research, which documented the need for second opinion in many instances to ensure the accuracy of the first opinion….Therefore, the accuracy of the analysis must be ensured and potential health hazards must be detected at the earliest possible point."[4] Although selection of a laboratory service is sometimes restricted to a degree by the third party payor, the Florida Legislature recognized the need to give physicians authority outside of the contractual HMO restrictions on choosing a laboratory as set forth in section 641.51, F.S., which allows physicians to seek a second opinion.

According to a representative from Fresenius, laboratory testing for dialysis patients is highly specialized. Factors, which may affect the selection of a clinical laboratory, include, but is not limited to:

- The Ability to provide extensive clinical databases;
- Provisions of customized laboratory reports and analyses for the attending nephrologist;
- Rapid result reporting capabilities (often within 24-48 hours of blood drawn);
- The use of normal ranges and panic values appropriate for kidney dialysis patients; and
- High quality test performance and reproducibility of results.

Medicare insures approximately 65-70% of patients diagnosed with end stage renal disease. Medicare Part A covers institutional facility charges (inpatient) and Medicare Part B covers physician and outpatient service charges (laboratory) and unless a Medicare HMO covers the patient, laboratory selection is not restricted. However, the laboratory must be a certified Medicare Provider for Medicare reimbursement to occur.

In fact, Medicare, the largest payor for renal dialysis services, has long recognized the critical role that laboratory testing plays in dialysis treatment and has set reimbursement for clinical laboratory tests for kidney dialysis patients in the form of a fixed composite rate, which also includes reimbursement for the dialysis procedure, paid directly to the dialysis clinic.

Medicare developed a fee schedule, clearly outlining both the type and quantity of tests that may be performed based on patient diagnosis and the set amount reimbursable, which are paid to clinical laboratories for laboratory testing. The state Medicaid program mirrors this type of reimbursement methodology, whereas, the composite rate for dialysis treatment is capped at $85 per visit for each dialysis treatment, which includes some laboratory testing.[5] As set forth in the Medicaid Provider's handbook, the Medicaid reimbursement policy,

[4] *Relationship between Dermatologists, Health Maintenance Organizations, and Clinical Laboratories,* House Committee on Health Care Licensing and Regulation, December 1999.
[5] Chapter 2001-253, Laws of Florida, General Appropriations Act.

laboratory testing is limited to the type and quantity of tests that are reimbursable.

Corporate Specific Information

ESRD Laboratories, currently owned by Dr. Mark Ginsburg, have had ongoing litigation stemming from the original purchase of an independently owned laboratory and several dialysis clinics in the South Florida area by Gambro Healthcare, Inc. The litigation history between Gambro and Dr. Mark Ginsburg actually involves three separate but overlapping lawsuits, the first of which was filed in November of 1996. Although these lawsuits involve several parties, they primarily involve two individuals, Dr. Mark Ginsburg and Dr. Bernie Pachter verses Gambro Healthcare, Inc. (Gambro). One of the three lawsuits has been settled and the other two lawsuits are ongoing. In the Appendix are copies of litigation filed by Gambro and Mark Ginsburg and the settlement agreement.

Federal Action Against ESRD Providers in Florida

Gambro Healthcare Laboratory Services, Inc., and Fresenius Medical Care, North America, have been investigated by the Department of Justice and settlement agreements reached by all parties. Because of those investigations, Gambro, Fresenius, and the Office of the Inspector General (OIG) of the United States Department of Health and Human Services have entered into “Corporate Integrity Agreements.”

Currently, the OIG is monitoring more than 450 corporate integrity agreements (CIAs) and settlements with integrity provisions. Virtually all types of health care providers have negotiated CIAs with the OIG, e.g., Nova Southeastern University in Fort Lauderdale, Yale University, Mt. Sinai School of Medicine, New York, and the New York City Fire Department Emergency Medical Service.

The OIG often imposes compliance obligations on health care providers and other entities as part of the settlement of Federal health care program investigations arising under a variety of civil false claims statutes. A provider or entity consents to these obligations as part of the civil settlement and in exchange for the OIG's agreement not to seek an exclusion of that health care provider or entity from participation in Medicare, Medicaid and other Federal health care programs. False claims submitted in violation of the False Claims Act or Civil Monetary Penalties Law give rise to the OIG’s permissive exclusion authority under 42 U.S.C.1320a-7(b)(7). Providers who settle these cases often deny that they were liable or that they committed the alleged conduct.

The typical term of a comprehensive corporate integrity agreement (CIA) is five years (three years for national project cases). These compliance measures seek to ensure the integrity of Federal health care program claims submitted by the

provider. The more comprehensive integrity agreements, which both Fresenius and Gambro are currently bound by, include requirements to:

- Hire a compliance officer/appoint a compliance committee;
- Develop written standards and policies;
- Implement a comprehensive employee-training program;
- Audit billings to Federal health care programs;
- Establish a confidential disclosure program;
- Restrict employment of ineligible persons; and
- Submit a variety of reports to the OIG.

While many CIAs have common elements, each agreement addresses, in part, the facts of the conduct at issue, and is tailored to comport with the existing capabilities of the provider. The integrity agreements often attempt to accommodate and recognize many of the elements of pre-existing voluntary compliance programs.

Both Gambro Healthcare Laboratories Services, Inc., and Fresenius Medical Care North American corporate integrity agreements are attached for review in the Appendix of this report.

FINDINGS AND CONCLUSIONS

Summary of Critical Points in the AHCA Study

Due to complaints presented to the 1999 Legislature, the Agency for Health Care Administration (AHCA) through Chapter 99-356 and Chapter 99-397, Laws of Florida, was required to study issues including:

- An analysis of the past and present utilization rates of clinical laboratory services for dialysis patients;
- Financial arrangements among kidney dialysis centers, their medical directors, any business relationships and affiliations of clinical laboratory services for dialysis patients in Florida; and
- The average annual revenue for dialysis patients for clinical laboratory services for the past 10 years.

The Agency was directed to report its findings to the Legislature by February 1, 2000. Subsequently, the agency issued the report, which concluded that additional time and investigative resources were necessary to adequately respond to the legislative directives. Of the issues the Legislature directed ACHA to investigate, the following concerns could have been addressed through current remedies:

- **Laboratory test utilization -** this information is a critical component of any investigation through AHCA's Inspector General's Office for fraud and abuse.
- **Financial Arrangements between dialysis facilities, medical directors and clinical laboratories -** All ESRD care providers in Florida are currently classified as Certified Medicare and Medicaid providers and are obligated under all contractual arrangements of such certification. The specifics of the contractual arrangements for Medicaid providers are set forth in section 409.907, F.S., Medicaid provider agreements. Statutorily, it is required that full and accurate disclosure be provided of any financial or ownership interest that the provider, or any principal, partner, or major shareholder thereof, may hold in any other Medicaid provider or health care related entity or any other entity that is licensed by the state to provide health or residential care and treatment to persons.

All aforementioned remedies are presented in detail within this report.

A draft copy of ACHA's report was obtained before the final report being released to the Legislature. Substantial changes were made. For example, according to the draft report, ESRD Laboratories, located in Fort Lauderdale, controlled over 30% of the clinical laboratory market in Florida, while at the same time, maintaining the position that "there needs to be increased competition among providers." Both reports are included in the Appendix.

Summary of Critical Points in USF Dialysis Study

The 2000 Legislature then appropriated "the sum of $230,000 from the Agency for Health Care Administration Tobacco Settlement Trust Fund to the Agency for Health Care Administration to contract with the University of South Florida to conduct a review of laboratory test utilization, any self-referral to clinical laboratories, financial arrangements among kidney dialysis centers, their medical directors, referring physicians, and any business relationships and affiliations with clinical laboratories, and the quality and effectiveness of kidney dialysis treatment in this state."

The 2001 Florida Dialysis Study by USF recognized that, "While all of the Legislature's stated concerns could not be addressed due to lack of subpoena power and the absence of mandatory standardized reporting requirements for dialysis organizations, this study has provided important and useful insight into areas of potential fraud,…."[6] thereby requiring further review by the Legislature.

The mandated study areas in which the Florida Legislature requested that the University of South Florida (USF) obtain information included:

- Laboratory test utilization;
- Financial arrangements between dialysis facilities, medical directors and clinical laboratories;
- Any self-referral of dialysis patients to clinical laboratories; and
- The quality and effectiveness of clinical dialysis treatment.

Of the issues the Legislature directed ACHA to investigate through the University of South Florida, all areas of concerns could have been addressed through current remedies:

- **Laboratory test utilization -** this information is a critical component of any investigation through AHCA's Inspector General's Office for fraud and abuse.
- **Financial Arrangements between dialysis facilities, medical directors and clinical laboratories -** All ESRD care providers in Florida are currently classified as Certified Medicare and Medicaid providers and are obligated under all contractual arrangements of such certification. The specifics of the contractual arrangements for Medicaid providers are set forth in section 409.907, F.S., Medicaid provider agreements. Statutorily, it is required that full and accurate disclosure be provided of any financial or ownership interest that the provider, or any principal, partner, or major shareholder thereof, may hold in any other Medicaid provider or health care related entity or any other entity that is licensed by the state to provide health or residential care and treatment to persons.

[6] *2001 Florida Dialysis Study,* Agency for Health Care Administration and the University of South Florida.

- **Any self-referral of dialysis patients to clinical laboratories -** through the required disclosure of financial arrangements of the Medicaid provider contract, it can be determined if any self-referral exist between the clinics and laboratory.
- **Quality and effectiveness of treatment -** in 1997, the Florida Legislature authorized a disease management program and directed the Agency to "select methods for implementing the program that included best practices, prevention strategies, clinical-practice improvement, clinical interventions and protocols, outcomes research, information technology, and other tools." The Florida disease management initiative has been designed to promote and measure: health outcomes; improved care; reduced inpatient hospitalization; reduced emergency room visits; reduced costs; and better educated providers and patients.

There are four major ESRD clinical laboratories providing services to dialysis patients in Florida. However, the USF Study limited the scope of its review to only three of the four clinical laboratories: Fresenius Medical Care; DaVita Inc.; and Gambro Healthcare, Inc. If information had been requested and received from ESRD Laboratories, the only Florida-based clinical laboratory, it would have provided an important control group for analysis of test utilization data, as ESRD Laboratories is a non-vertically integrated clinical laboratory.

The USF Study draws a conclusion based upon “potential opportunities for fraud and abuse” without a discussion of existing remedies in place to prevent fraud and abuse. Such existing remedies or controls in the system that minimize and prevent abuse, include, but are not limited to:

- State regulations:
    - Medicaid Provider Contracts;
    - Medicaid Reimbursement Methodology;
    - Medicaid Program Integrity;
    - Disease Management Organization; and
    - Clinical Licensing/ ACHA license all laboratories and acts as the certifying agency for the federal Clinical Laboratory Improvement Amendment (CLIA) Certification.

- Federal regulations:
    - Medicare Provider Contracts;
    - Medicare & Medicaid Program Integrity Unit; and
    - Network 7

- Federal regulatory and enforcement agencies, which agencies enforce existing state and federal anti-kickback and self-referral laws;

- Pre-payment and post-payment reviews by CMS carriers and other third party payors; and

- The existence of corporate integrity agreements between some of the dialysis companies and the federal government, which agreements have similar provisions as the companies' voluntary compliance programs.

Moreover, the Dialysis Study failed to report that the dialysis companies have cooperated with the federal government to resolve historic issues and have maintained their standing as Medicare providers.

While the federal government is the primary payor of health services of patients with ESRD, the USF report failed to recognize or discuss that all ESRD providers are also Florida Medicaid Providers with underlying contractual regulations.

State Regulation of ESRD Providers

Clinical Licensing

As set forth in chapter 483, F.S., known as the "The Florida Clinical Laboratory Law," the Agency for Health Care Administration administers the state licensure and federal certification of clinical laboratories in the State of Florida. All facilities, including physician offices performing waived or non-waived clinical laboratory testing, are required to obtain a federal Clinical Laboratory Improvement Amendment (CLIA) certificate and a state clinical laboratory license. Initial and biennial inspections are required for facilities performing non-waived testing. The state clinical laboratory license must be issued before the laboratory is authorized to perform testing.

Facilities performing non-waived clinical laboratory testing must submit level two background screening forms and fees for the laboratory director and financial officer. The level two background screening consists of a fingerprint check by the Florida Department of Law Enforcement (FDLE) and the Federal Bureau of Investigation (FBI).

While the laboratories performing services for ESRD care are licensed, dialysis clinics are not, and are governed similar to that of a physician's office.

Medicaid Provider Agreements (MPAs)

Medicaid is the state and federal partnership that provides health coverage for selected categories of people with low incomes. Its purpose is to improve the health of people who might otherwise go without medical care for themselves and their children. Medicaid is different in every state. In Florida, the Agency for Health Care Administration (the Agency) develops and carries out policies related to the Medicaid program. Less than one-tenth of the entire state

Medicaid budget is spent on patients diagnosed with end stage renal disease, approximately $113,000,000 is spent in treating these patients from an estimated $10 billion dollar state Medicaid budget. According to data provided to committee staff, of the $113,000,000, approximately $4-5 million is actually spent on direct dialysis care and laboratory costs, the other costs are associated with hospitalization, pharmaceuticals, and transportation for these patients.

Medicaid is different from Medicare. Medicare is a federal health insurance program for people who are age 65 or older, or disabled and individuals diagnosed with ESRD. The federal Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), formerly known as Health Care Financing Administration (HCFA) administers Medicare. Eligibility for Medicare is not based on the person's income or assets.

All ESRD care providers in Florida are currently classified as Certified Medicare and Medicaid providers and are obligated under all contractual arrangements of such certification. The specifics of the contractual arrangements for Medicaid providers are set forth in section 409.907, F.S., Medicaid provider agreements. Statutorily, the agency may make payments for medical assistance to Medicaid recipients only to an individual or entity who has a provider agreement in effect with the agency, who is performing services or supplying goods in accordance with federal, state, and local law.

Each provider agreement requires the provider to comply fully with all state and federal laws pertaining to the Medicaid program, as well as all federal, state, and local laws pertaining to licensure.

Each provider agreement is a voluntary contract between the agency and the provider, in which the provider agrees to comply with all laws and rules pertaining to the Medicaid program when furnishing a service or goods to a Medicaid recipient and the agency agrees to pay a sum, determined by fee schedule, payment methodology, or other manner, for the service or goods provided to the Medicaid recipient. Each provider agreement is effective for a stipulated period, is terminable by either party after reasonable notice, and is renewable by mutual agreement.

The provider agreement may permit the agency, the Attorney General, the Federal Government, and the authorized agents of each of these entities access to all Medicaid-related information. Medicaid information, which among other things, **include utilization rates, and other documents** that may be in the form of records, logs, documents, or computer files, and other information pertaining to services or goods billed to the Medicaid program. In addition, the agency, the Attorney General, the Federal Government and it’s authorized agents may request information including access to all patient records and other provider information if the provider cannot easily separate records for Medicaid patients from other records.

The **agency may adopt, and include in the provider agreement, such other requirements and stipulations on either party as the agency finds necessary to properly and efficiently administer the Medicaid program.**

A Medicaid provider agreement may be revoked, at the option of the agency, as the result of a change of ownership of any facility, association, partnership, or other entity named as the provider in the provider agreement. A provider shall give the agency 60 days' notice before making any change in ownership of the entity named in the provider agreement as the provider.

The agency may require, as a condition of participating in the Medicaid program and before entering into the provider agreement, that the provider submit information concerning the professional, business, and personal background of the provider and permit an onsite inspection of the provider's service location by agency staff or other personnel designated by the agency to perform this function. The information must include, information concerning any prior violation, fine, suspension, termination, or other administrative action taken under the Medicaid laws, rules, or regulations of this state or of any other state or the Federal Government; any prior violation of the laws, rules, or regulations relating to the Medicare program; any prior violation of the rules or regulations of any other public or private insurer; and any prior violation of the laws, rules, or regulations of any regulatory body of this or any other state. **This stipulated requirement is evident among the dialysis providers today, whereby, after federal investigations, most providers hired new personnel to implement the recommended changes by the federal government.**

The information must also include full and accurate disclosure of any financial or ownership interest that the provider, or any principal, partner, or major shareholder thereof, may hold in any other Medicaid provider or health care related entity or any other entity that is licensed by the state to provide health or residential care and treatment to persons. In other words, the agency has the right, through the Medicaid provider agreement, to request financial and ownership interest information that the medical director may have with not only the dialysis clinic, but with the laboratory as well. <u>It is unclear as to why ACHA did not pursue this route when asked to study this issue in 1999 in regards to the financial relationship request for information.</u>

Pursuant to s. 409.907(8)(a), F.S., each provider, or each principal of the provider if the provider is a corporation, partnership, association, or other entity, seeking to participate in the Medicaid program must submit a complete set of his or her fingerprints to the agency for the purpose of conducting a criminal history record check. Principals of the provider include any officer, director, billing agent, **managing employee,** or affiliated person, or any partner or shareholder who has an ownership interest equal to 5 percent or more in the provider.

Notwithstanding the above, the agency may require a background check for any person reasonably suspected by the agency to have been convicted of a crime.

In considering whether to deny or award a contract, the agency may consider whether the provider, or any officer, director, agent, managing employee, or affiliated person, or any partner or shareholder having an ownership interest equal to 5 percent or greater in the provider if the provider is a corporation, partnership, or other business entity, has:

- Made a false representation or omission of any material fact in making the application, including the submission of an application that conceals the controlling or ownership interest of any officer, director, agent, managing employee, affiliated person, or partner or shareholder who may not be eligible to participate;
- Been or is currently excluded, suspended, terminated from, or has involuntarily withdrawn from participation in, Florida's Medicaid program or any other state's Medicaid program, or from participation in any other governmental or private health care or health insurance program;
- Been convicted of a criminal offense relating to the delivery of any goods or services under Medicaid or Medicare or any other public or private health care or health insurance program including the performance of management or administrative services relating to the delivery of goods or services under any such program;
- Been convicted under federal or state law of a criminal offense related to the neglect or abuse of a patient in connection with the delivery of any health care goods or services;
- Been convicted under federal or state law of a criminal offense relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance;
- Been convicted of any criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct;
- Been convicted under federal or state law of a crime punishable by imprisonment of a year or more which involves moral turpitude;
- Been convicted in connection with the interference or obstruction of any investigation into any criminal offense listed in this subsection;
- Been found to have violated federal or state laws, rules, or regulations governing Florida's Medicaid program or any other state's Medicaid program, the Medicare program, or any other publicly funded federal or state health care or health insurance program, and been sanctioned accordingly;
- Been previously found by a licensing, certifying, or professional standards board or agency to have violated the standards or conditions relating to licensure or certification or the quality of services provided; or
- Failed to pay any fine or overpayment properly assessed under the Medicaid program in which no appeal is pending or after resolution of the

proceeding by stipulation or agreement, unless the agency has issued a specific letter of forgiveness or has approved a repayment schedule to which the provider agrees to adhere.

Section 409.908, F.S., establishes the Reimbursement for Medicaid Providers provision which specifies that all Medicaid payments are subject to specific appropriations, and the agency shall reimburse Medicaid providers, in accordance with state and federal law, according to methodologies set forth in the rules of the agency and in policy manuals and handbooks. These methodologies may include fee schedules, reimbursement methods based on cost reporting, negotiated fees, competitive bidding pursuant to s. 287.057, F.S., and other mechanisms the agency considers efficient and effective for purchasing services or goods on behalf of recipients. Payment for Medicaid compensable services made on behalf of Medicaid eligible persons is subject to the availability of moneys and any limitations or directions provided for in the General Appropriations Act or chapter 216, F.S.

Providers of independent laboratory services are reimbursed at a rate, which is the least of the amount billed, by the provider, the provider's usual and customary charge, or the Medicaid maximum allowable fee established by the agency.

As required by statute, Medicaid shall pay all deductibles and coinsurance for Medicare-eligible recipients receiving freestanding end stage renal dialysis center services, therefore, all patients being treated for ESRD in Florida that are covered by Medicare are also covered by Medicaid. In that respect, any and all financial relationship concerns that the state has with providers of ESRD care is more appropriately addressed through the Medicaid Program Integrity Office and the Provider Enrollment Office.

Disease Management Organizations (DMOs)

In addition to all the regulations set forth in the Medicaid provider contracts in 1997, the Florida Legislature authorized a disease management program and directed the Agency to "select methods for implementing the program that included best practices, prevention strategies, clinical-practice improvement, clinical interventions and protocols, outcomes research, information technology, and other tools." The Florida disease management initiative has been designed to promote and measure: health outcomes; improved care; reduced inpatient hospitalization; reduced emergency room visits; **reduced costs;** and better educated providers and patients. It is also expected that the disease management initiative will bring an enhanced connection between the patient and the provider, making a significant impact on health outcomes and improved quality of life for patients with chronic diseases.

The Agency for Health Care Administration has contracted with disease management organizations to provide disease management services to Medicaid recipients enrolled in the Primary Care Case Management Program (MediPass) who have been diagnosed with diabetes, HIV/AIDS, asthma, hemophilia, congestive heart failure and **end stage renal disease.**

The Medicaid disease management projects are available only to Medicaid recipients enrolled in MediPass. The MediPass population represents over 560,000 of the more than 1.5 million Florida Medicaid recipients. According to the data provided by AHCA to the committee staff, out of the approximate **7,000 Medicaid recipients with End Stage Renal Disease, 3-4,000 of those patients are monitored through the ESRD DMO.** All MediPass recipients meeting the criteria for participation in a disease management program are automatically enrolled in the disease management initiative, but can disenroll at anytime.

Results of disease management studies conducted around the country indicate that closely managing patients with chronic diseases can reduce the higher cost services these patients often require and at the same time improve quality of life for the patient. Disease management also can prevent or delay the onset of the more severe stages of a disease.

The Agency identifies potential MediPass disease management recipients through paid claims. Prospective recipients are notified by the Agency and the disease management organization that they are eligible for participation in the program and are advised of the additional care management benefits that are a part of the disease management initiative. The disease management care managers become an extension of the physician's services by helping the enrolled patients better understand their diseases and make necessary lifestyle changes with the goal of self-management. Providers are informed of their enrolled patients' progress through ongoing reports. In addition, leading experts in the treatment of each disease state provide providers with clinical practice guidelines developed.

The Agency encourages MediPass physicians and entities to work closely with the disease management organizations to make this concept a successful effort. This program should prove to be beneficial to the patient, the provider, and Medicaid. According to AHCA, the disease management initiative is expected to ultimately improve the health and well being of MediPass patients, provide additional resources to MediPass providers, and reduce costs associated with patients who have a chronic disease, specifically, end stage renal disease.

Medicare and Medicaid Comprehensive Plan for Program Integrity

Promoting the integrity of Medicare and Medicaid is a top priority of the Centers for Medicare and Medicaid (CMS) [formerly known as the Health Care Financing Administration (HCFA)]. As these programs have grown in size and complexity, so have the importance and the challenges of that responsibility. According to CMS, achieving program integrity now requires the active involvement of every component of CMS, and effective coordination with partners, which include contractors, providers, beneficiaries, and law enforcement.

The program integrity goal is straightforward striving in every case to pay the right amount, to a legitimate provider, for covered, reasonable, and necessary services, provided to an eligible beneficiary. In particular, HCFA set a goal of reducing claims payment error rate by 50 percent by the year 2002. To achieve this goal, they followed four parallel strategies:

1) preventing fraud through effective enrollment and through education of providers and beneficiaries;
2) early detection through, for example, medical review and post-pay data analysis;
3) close coordination with partners, including contractors and law enforcement agencies; and
4) fair and firm enforcement policies.

According to data from CMS, the vast majority of providers and suppliers are honest. Educating providers and suppliers as to the often-complex set of rules that protect the integrity of Medicare and Medicaid is key to the program integrity efforts. Assuring that they direct their enforcement efforts only against purposeful or knowing misconduct is another hallmark of the program integrity strategy.

In May 1995, HCFA inaugurated a renewed anti-fraud effort with Operation Restore Trust, a two-year demonstration in which they collaborated with law enforcement agencies to target Medicare and Medicaid fraud in five of the largest states. Operation Restore Trust led to record levels of criminal convictions, fines, exclusions and, perhaps more importantly, a new and collaborative way of approaching program integrity. The providers of ESRD in Florida were subject to these investigations. The lessons they learned through Operation Restore Trust have become part of the way they do business today. As part of Operation Restore Trust, CMS's National Medicaid Fraud and Abuse Initiative issued its report focusing upon anti-fraud efforts in Medicaid, an important companion document to the Comprehensive Plan. The new funds and authorities provided in the Health Insurance Portability and Accountability Act of 1996 and the Balanced Budget Act of 1997, which gave them significant new tools in the fight against fraud, have further enhanced CMS’s anti-fraud efforts.

To solicit new ideas in their anti-fraud effort, HCFA sponsored a national conference in March 1998. This event brought together representatives of the health care community, insurance companies, government agencies, and members of Congress to discuss best practices and new strategies for confronting fraud and abuse. Out of that conference came many constructive lessons, some of which have already been implemented, as well as the beginnings of the Comprehensive Plan for Program Integrity.

The Comprehensive Plan outlines key program integrity initiatives which represents a marriage of new ideas and time-tested approaches, it addresses the five management areas and five benefit categories where there is the greatest potential for improved program integrity and the greatest potential to reduce error rate.

Medicare Provider Contracts

The Medicare statute was amended in 1972 to specifically authorize coverage for individuals with diabetes; hypertension or other diseases that result in sever impairment of kidney function known as ESRD, beginning in 1973. Since then, Medicare has paid for some $126 billion worth of services for a total of more than one million ESRD patients and currently over 300,000 patients are being served nationally.[7] Promoting provider integrity is at the heart of any effort to ensure that Medicare beneficiaries obtain quality medical care cost effectively. Previously, many providers have regarded participation in Medicare as an entitlement. This is because they could obtain provider status and billing numbers without having to meet any standards that would ensure that they are financially sound, accountable business partners. Once providers are billing Medicare, it has been difficult for the federal government to find and penalize providers that are bad business partners or otherwise raise program integrity questions.

CMS's focus in now concentrating on enrolling accountable and financially sound providers in the first place in order to promote the highest possible level of provider integrity in the Medicare program. CMS will concentrate its effort on developing a proactive provider enrollment and re-enrollment process. This will mean that providers must meet standards to participate in and to continue to participate in Medicare.

Provider enrollment refers to all of the activities, which occur before a provider is allowed to participate in the Medicare and Medicaid programs. The information gathered during the March 1998 fraud and abuse conference and the experience from the Operation Restore Trust (ORT) Anti-Fraud initiative, internal CMS analyses (e.g., Miami Field Office), and reports by the General Accounting Office

[7] Testimony of Jeffrey Kang, M.D., director of Office of Clinical Standards and Quality Health Care Financing Administration, on the Medicare End Stage Renal Disease Program, before the US Senate Special Committee on Aging, June 26, 2000.

(GAO) and the Office of the Inspector General (OIG) point out prior weaknesses in provider enrollment processes.

According to HCFA's website (www.hfca.gov), many participants at the National Fraud, Waste and Abuse Conference held in March 1998 recommended that CMS strengthen provider enrollment activities. Enhancing current provider enrollment activities is a very effective way to make the Medicare and Medicaid programs less vulnerable to unscrupulous providers of all types and stop fraud and abuse, simply by keeping them out of the program. Developing stricter standards and stronger conditions of participation, conducting onsite visits to verify legitimacy and compliance with standards, requiring surety bonds, and collecting better ownership and financial solvency information are all examples of activities which enhance CMS's ability to prevent bad providers from entering the programs.

While through Operation Restore Trust, CMS suspended payment and terminated the provider numbers of a number of Community Mental Health Centers in response to reviews conducted by HCFA and the OIG. However, the providers of ESRD that were investigated under the same project have all maintained their status as Medicare Providers through the implementation of their respective corporate integrity agreements.

Network 7

As demonstrated in this report, not only are the ESRD Providers subject to the state Medicaid provider regulations with the corresponding oversight of the Disease Management Organization; so, to, the federal program, Medicare also has established an oversight agency known as Network 7. "Congress, in 1978, established the ESRD Network organization Program to provide coordination and guidance, and assure effective and efficient administration of the Medicare renal disease benefits. ESRD Network responsibilities include:

- Promoting criteria and standards for quality and appropriateness of care;
- Encouraging the use of treatment settings that are compatible with patients successful rehabilitation;
- Receiving, evaluating, and resolving grievances involving ESRD patient care and/or services; and
- Establishing a Network Council and Medical Review Board to represent area dialysis facilities.

This program was recodified in 1986 when Congress redefined ESRD Network areas. Funding for ESRD Networks comes from withholding 50 cents per patient per dialysis treatment from payments to dialysis facilities. There are currently 18 ESRD Network Organization areas, and fiscal year 2000 ESRD Network funding

is $17 million."[8] The End Stage Renal Disease Network of Florida is a contractor for the federal Centers for Medicare and Medicaid (CMS), which oversees the Medicare ESRD program in Florida and is known as Network 7.

The Network serves both as a monitoring agency and as a bridge between the federal government, ESRD providers and patients. The Network has implement informational and educational programs concerning continuous quality improvement principles and practices that will help dialysis and transplant providers assess, evaluate and measurably improve the care provided to their ESRD patients. In addition, the Network assures that the submission of CMS forms comply with CMS's acceptable rates for timeliness and accuracy; and helps to maintain a continue high level of cooperation between the Network and the state survey agency.

The objectives of Network 7 are to:

- Assess and improve the quality of care provided to ESRD patients;
- Conduct reviews of providers utilizing quality of care indicators to assure quality medical care for Medicare ESRD patients;
- Develop and educate the renal community about information on patterns of occurrence, care and outcomes to measurably improve the care and health outcomes for ESRD patients;
- Evaluate the process providers use to assess patients for appropriate treatment modalities;
- Track and profile CMS form compliance rates by provider;
- Notify providers of their compliance rates;
- Assist providers who need to improve their compliance rates;
- Maintain a Memorandum or Understanding between the ESRD Network of Florida and the state survey agency, the Agency for Health Care Administration (AHCA); and
- Share with the CMS regional office and state survey agency information on profiles and patterns of care and outcomes that can be used by the state survey agency in its ESRD Medicare survey and certification activities.

[8] Testimony of Jeffrey Kang, M.D., Director of Office of Clinical Standards and Quality Health Care Financing Administration, on the Medicare End Stage Renal Disease Program, before the US Senate Special Committee on Aging, June 26, 2000.

Stark Amendment

In 1992, the Federal Government adopted the "Stark Amendment", as set forth in 42 U.S.C. § 1395nn, and in 1995, regulations that created exceptions for ESRD services were established. These provisions prohibit physicians from making referrals to entities with which they have a financial relationship for the furnishing of certain services that might otherwise be covered by Medicare or Medicaid. The statute also provides that an entity may not bill for services rendered pursuant to a prohibited referral. The Stark statute is a strict liability statute and payment may be denied for prohibited referrals and refunds may be required for money collected pursuant to prohibited referrals regardless of the physician's intent in making the referral.

The exemption created in 1995, permits referrals for laboratory services furnished in an ESRD facility that are included in the ESRD composite rate as set forth in 42, U.S.C. § 411.355 (d); and 60 Fed. Reg. 41, 939 and 41, 975 (August 14, 1995). The preamble of the amendment provides background information concerning the classes of clinical laboratory test received by hemodialysis patients. As expressed in the 1998 preamble, the rationale supporting this exception is that referrals for certain clinical laboratory services furnished in an ESRD facility do not involve a risk of abuse when payments for these services are included in the ESRD composite payment rate. The January 9, 1998, regulations retained the exception for ESRD services and extended this exception to all the ten additional designated health services adopted in 1998, if payment for that designated health service is included in the ESRD composite rate as set forth in Fed. Reg.1, 659, 1,666 (January 9, 1998).

On January 4, 2001, CMS (formally known as HCFA) issued final Stark regulations, not effective until January 4, 2002, that address the ESRD exception. CMS promulgated rules for this exception under 42 U.S.C. § 411.355(d) for clinical laboratory services furnished in an ESRD facility if payment for those services excludes services that are reimbursed by Medicare as a part of the composite rate, as set forth in 42, U.S.C. §411.351.

As well, the Stark amendment addresses the indirect financial relationship where a physician has an ownership interest in an organization, which in turn has an ownership interest in laboratory entity as set forth in 57 Fed. Reg., 8,595, 8, 596 (March 11, 1992).

In addition, the August 14, 1995, preamble provides a few hypotheticals dealing with brother/sister corporate relationships and the Stark implications rose when services are referred from one entity to another as set forth in 60 Fed. Reg. 41, 944, 41, 945. The majority of these examples concern physicians with ownership (rather than compensation) relationship with the entities to which the physician refers patients. However, the preamble indicates, "Our analysis of corporate

relationships would also involve any compensation aspects of the relationship." As set forth in 60 Fed. Reg. 41, 945.

The January 9, 1998, preamble discusses when a referring physician receives compensation from an entity that is owned or controlled by a party that also owns a designated health service provider as set forth in 63, Fed. Reg. 1,659, 1,710.

On January 4, 2001, CMS issued Phase 1 of its long awaited final recommendations interpreting the federal self-referral law known as Stark II. This law prohibits physicians from referring Medicare and Medicaid patients needing specific health services to entities with which the physician has an ownership, investment, or compensation relationship. Accompanying final regulations to date also address indirect compensation relationships, explaining that CMS intends to trace the compensation paid by an entity furnishing designated health services through other entities, regardless of how the compensation might be transformed as set forth in 66, Fed. Reg. 856, 864. The January 4, 2001, regulations were substantially revised from the January 9, 1998, proposed regulations concerning indirect compensation relationships. Most notably, the final regulations impose a knowledge requirement such that liability for Stark violations will not be extended between entities furnishing the designated health services and the entity with whom the physician has a financial relationship unless the designated health service provider has knowledge of the physician's compensation relationship with the entity as set forth in 66 Fed. Reg. 856, 864. The final regulations also create a new exception for certain indirect compensation arrangements that are generally consistent with the new fair market value exception for direct compensation arrangements as set forth in 66 Fed. Reg. At 865. In addition, the preamble and regulations add a definition of indirect compensation arrangements as set forth in 66 Fed. Reg. At 865-870.

Existing Remedies for Fraud and Abuse in Health Care

"The Legislature, the Attorney General's Office (specifically the Medicaid Fraud Control Unit), the Agency for Health Care Administration, the Office of Statewide Prosecutor, and the federal government have taken numerous steps over the past several years to combat fraud and abuse within the Florida Medicaid program. Past initiatives have included: claims payment analyses and controls; provider surety bonds and financial background checks; on-site provider visits; Level I and Level II criminal background checks; additional Medicaid Management Information System edits; and improved interagency coordination. More recent initiatives include: pharmacy audits, including on-site audits and audits specific to overpayments; an explanation of medical benefits mailing to some recipients;…enhanced claims analysis and automated fraud and abuse detection capabilities; additional pharmacy fraud and abuse controls, including surety bonds and on-site inspections prior to entering provider agreements; fraud detection system enhancements to identify patterns of fraud; and Physician

Practice Pattern review, including drug usage evaluation, prescribing profiles, physician education, and outcomes analysis. Medicaid fraud issues adopted by the 2000 Legislature addressed additional surety bond requirements based on volume of business for certain Medicaid providers, additional authority for AHCA to deny Medicaid provider applications, and easier access to otherwise confidential patient information by the Attorney General's Medicaid Fraud Control Unit." [9]

Medicaid Program Integrity Unit

The Medicaid program is administered by the Agency for Health Care Administration (AHCA) and is authorized by Chapter 409, F.S., and the corresponding rules are promulgated in Chapter 59-G, Florida Administrative Code. Specifically, the Office of Program Integrity is under AHCA's Inspector General and administers Medicaid's fraud and abuse initiatives.

As set forth in section 409.913, F.S., **Oversight of the integrity of the Medicaid program,** the agency operates a program to oversee the activities of Florida Medicaid recipients, and providers and their representatives, to ensure that fraudulent and abusive behavior and neglect of recipients occur to the minimum extent possible, and to recover overpayments and impose sanctions as appropriate.

According to this section, "Abuse" is defined as meaning:

- Provider practices that are inconsistent with generally accepted business or medical practices and that result in an unnecessary cost to the Medicaid program or in reimbursement for goods or services that are not medically necessary or that fail to meet professionally recognized standards for health care.
- Recipient practices that result in unnecessary cost to the Medicaid program.

"Fraud" is defined as meaning an intentional deception or misrepresentation made by a person with the knowledge that the deception results in unauthorized benefit to herself or himself or another person. The term includes any act that constitutes fraud under applicable federal or state law.

In order to bill for Medicaid reimbursement, the service provider must demonstrate that the service is medically necessary. In section 409.913(1)(c), F.S., "Medical necessity" or "medically necessary" means any goods or services necessary to palliate the effects of a terminal condition, or to prevent, diagnose, correct, cure, alleviate, or preclude deterioration of a condition that threatens life, causes pain or suffering, or results in illness or infirmity, which goods or services are provided in accordance with generally accepted standards

[9] The Florida House of Representatives Historical Policy Briefing 2000.

of medical practice. For purposes of determining Medicaid reimbursement, the agency is the final arbiter of medical necessity. Determinations of medical necessity must be made by a licensed physician employed by or under contract with the agency and must be based upon information available at the time the goods or services are provided.

Furthermore, section 409.913, F.S., authorizes AHCA to conduct, or may contract for, prepayment review of provider claims to ensure cost-effective purchasing, billing, and provision of care to Medicaid recipients. Such prepayment reviews may be conducted as determined appropriate by the agency, **without any suspicion or allegation of fraud, abuse, or neglect.**

Upon the suspicion of fraud or abuse, or any suspected criminal violation identified by the agency, this issue must be referred to the Medicaid Fraud Control Unit of the Office of the Attorney General for investigation. The agency and the Attorney General shall enter into a memorandum of understanding, which must include, but need not be limited to, a protocol for regularly sharing information and coordinating casework. The protocol must establish a procedure for the referral by the agency of cases involving suspected Medicaid fraud to the Medicaid Fraud Control Unit for investigation, and the return to the agency of those cases where investigation determines that administrative action by the agency is appropriate.

As well, a Medicaid provider is subject to having goods and services that are paid for by the Medicaid program reviewed by an appropriate peer-review organization designated by the agency. The written findings of the applicable peer-review organization are admissible in any court or administrative proceeding as evidence of medical necessity or the lack thereof.

When presenting a claim for payment under the Medicaid program, a provider has an affirmative duty to supervise the provision of, and be responsible for, goods and services claimed to have been provided, to supervise and be responsible for preparation and submission of the claim, and to present a claim that is true and accurate and that is for goods and services that:

- Have actually been furnished to the recipient by the provider prior to submitting the claim;
- Are Medicaid-covered goods or services that are medically necessary;
- Are of a quality comparable to those furnished to the public by the provider's peers;
- Have not been billed in whole or in part to a recipient or a recipient's responsible party, except for such co-payments, coinsurance, or deductibles as are authorized by the agency;
- Are provided in accordance with applicable provisions of all Medicaid rules, regulations, handbooks, and policies and in accordance with federal, state, and local law; and

- Are documented by records made at the time the goods or services were provided, demonstrating the medical necessity for the goods or services rendered. Medicaid goods or services are excessive or not medically necessary unless both the medical basis and the specific need for them are fully and properly documented in the recipient's medical record.

The agency may require repayment for inappropriate, medically unnecessary, or excessive goods or services from the person furnishing them, the person under whose supervision they were furnished, or the person causing them to be furnished.

The complaint and all information obtained pursuant to an investigation of a Medicaid provider, or the authorized representative or agent of a provider, relating to an allegation of fraud, abuse, or neglect are confidential and exempt from the provisions of s. 119.07(1), F.S.:

- Until the agency takes final agency action with respect to the provider and requires repayment of any overpayment, or imposes an administrative sanction;
- Until the Attorney General refers the case for criminal prosecution;
- Until 10 days after the complaint is determined without merit; or
- At all times if the complaint or information is otherwise protected by law.

Under these provisions, the agency may terminate participation of a Medicaid provider in the Medicaid program and may seek civil remedies or impose other administrative sanctions against a Medicaid provider, if the provider has been:

- Convicted of a criminal offense related to the delivery of any health care goods or services, including the performance of management or administrative functions relating to the delivery of health care goods or services;
- Convicted of a criminal offense under federal law or the law of any state relating to the practice of the provider's profession; or
- Found by a court of competent jurisdiction to have neglected or physically abused a patient in connection with the delivery of health care goods or services.

Most importantly, if a provider has been suspended or terminated from participation in the Medicaid program or the Medicare program by the Federal Government or any state, the agency must immediately suspend or terminate, as appropriate, the provider's participation in the Florida Medicaid program for a period no less than that imposed by the Federal Government or any other state, and may not enroll such provider in the Florida Medicaid program while such foreign suspension or termination remains in effect. This sanction is in addition to all other remedies provided by law. Therefore, if the primary payor of services

for end stage renal disease (Medicare) terminates the Medicare certification, then the state automatically terminates the Medicaid provider agreement.

Pursuant to section 409.920(2)(e) and (f), F.S., Medicaid provider fraud, it is unlawful to:

- Knowingly solicit, offer, pay, or receive any remuneration, including any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made, in whole or in part, under the Medicaid program, or in return for obtaining, purchasing, leasing, ordering, or arranging for or recommending, obtaining, purchasing, leasing, or ordering any goods, facility, item, or service, for which payment may be made, in whole or in part, under the Medicaid program.

- Knowingly submit false or misleading information or statements to the Medicaid program for being accepted as a Medicaid provider.

A person who violates these provisions commits a felony of the third degree, punishable as provided in ss. 775.082, 775.083, or 775.084, F.S.

Subsection (7) of s. 409.920, F.S., further authorizes the Attorney General to conduct a statewide program of Medicaid fraud control. To accomplish this purpose, the Attorney General **shall**:

- Investigate the possible criminal violation of any applicable state law pertaining to fraud in the administration of the Medicaid program, in the provision of medical assistance, or in the activities of providers of health care under the Medicaid program.
- Investigate the alleged abuse or neglect of patients in health care facilities receiving payments under the Medicaid program, in coordination with the agency.
- Investigate the alleged misappropriation of patients' private funds in health care facilities receiving payments under the Medicaid program.
- Refer to the Office of Statewide Prosecution or the appropriate state attorney all violations indicating a substantial potential for criminal prosecution.
- Refer to the agency all suspected abusive activities not of a criminal nature.
- Refer to the agency for collection each instance of overpayment to a provider of health care under the Medicaid program, which is discovered during the course of an investigation.
- Safeguard the privacy rights of all individuals and provide safeguards to prevent the use of patient medical records for any reason beyond the

scope of a specific investigation for fraud or abuse, or both, without the patient's written consent.

Finally, in carrying out the duties and responsibilities under subsection (8), the Attorney General **may**:

- Enter upon the premises of any health care provider, excluding a physician, participating in the Medicaid program to examine all accounts and records that may, in any manner, be relevant in determining the existence of fraud in the Medicaid program, to investigate alleged abuse or neglect of patients, or to investigate alleged misappropriation of patients' private funds. A participating physician is required to make available any accounts or records that may, in any manner, be relevant in determining the existence of fraud in the Medicaid program. The accounts or records of a non-Medicaid patient may not be reviewed by, or turned over to, the Attorney General without the patient's written consent.
- **Subpoena witnesses or materials, including medical records relating to Medicaid recipients, within or outside the state and, through any duly designated employee, administer oaths and affirmations and collect evidence for possible use in either civil or criminal judicial proceedings.**
- Request and receive the assistance of any state attorney or law enforcement agency in the investigation and prosecution of any violation of this section.

The State of Florida views such activity of Medicaid fraud and abuse as criminal activity, and therefore has provided that the investigators employed by the Medicaid Fraud Control Unit, who are certified pursuant to s. 943.1395, F.S., are deemed law enforcement officers, as set forth in s. 409.9205, F.S. This section authorizes that all investigators have the authority to conduct criminal investigations, bear arms, make arrests, and apply for, serve, and execute search warrants, arrest warrants, capias, and other process throughout the state pertaining to Medicaid fraud as described in this chapter. The Attorney General shall provide reasonable notice of criminal investigations conducted by the Medicaid Fraud Control Unit to, and coordinate those investigations with, the sheriffs of the respective counties. Investigators employed by the Medicaid Fraud Control Unit are not eligible for membership in the Special Risk Class of the Florida Retirement System under s. 121.0515, F.S.

Health Care Antitrust Protections

"The federal and state governments both regulate business activities under their respective antitrust laws. Antitrust regulation is intended to discourage monopolies and control the exercise of "monopoly power," meaning the power to fix prices and exclude competition. The application of antitrust laws to the health care sector, a relatively recent phenomenon, has increased as the health care

market has been restructured and market competition has increased. Antitrust issues arise not from the actual delivery of care, but from the economic and business relationships that prevail in the health care industry.

Before 1975, the health care industry was not viewed as commerce, but as a "learned profession" regulated under state law to which antitrust laws did not apply. The United States Supreme Court's decision in *Goldfarb v. Virginia State Bar*, 42 U.S. 773 (1975), held that the learned professions are engaged in commerce and do not have an exemption from antitrust laws. The *Goldfarb* decision has had an effect on health care policy by providing the background for competition and in effect has revolutionized the notion that health care providers could be trusted to determine the framework under which health care is provided. After *Goldfarb*, **health care competitors would potentially be in violation of antitrust law for business activities in the provision of health care services that restrained competition.** *Goldfarb* allowed antitrust enforcement in an industry that regulated itself without market forces and, in effect, opened the door to competition in the health care industry, by making providers accountable to consumers for cost as well as the quality of their services.

Federal antitrust laws (the Sherman Antitrust Act, 15 U.S.C.A. §§1-7, the Clayton Act, 15 U.S.C.A. §§12-27 and the Federal Trade Commission Act, 15 U.S.C.A. §§45) prohibit anti-competitive conduct and are enforced by the U.S. Department of Justice and the Federal Trade Commission (FTC). In September 1993, both agencies released antitrust enforcement guidelines, which created "safety zones" for six specific merger or joint activities and provided additional guidance for similar activities falling outside of the safety zones. The safety zones represent certain acceptable collaborative activities, which the federal government will not challenge. Both federal agencies have issued new and revised statements of enforcement policy and analytical principles relating to health care and antitrust since 1993.

The Florida Antitrust Act of 1980 (ch. 542, F.S.) and other antitrust laws are enforced by the Department of Legal Affairs administered by the Attorney General.

Florida Health Care Community Antitrust Guidance Act

In 1996, the Florida Legislature created the Florida Health Care Community Antitrust Guidance Act, codified at s. 408.18, F.S., to provide a mechanism for members of the health care community who desire antitrust guidance to request a review of their proposed business activities by the Attorney General's office. The act defines "health care community" to include all licensed health care providers, insurers, networks, purchasers, and other participants in the health care system. **"Antitrust no-action letter"** is defined to mean a letter that states the intention of the Attorney General's office not to take antitrust enforcement

actions with respect to the requesting party, based on the facts then presented, as of the date the letter is issued.

To obtain the review, a member of the health care community must submit a written request for an antitrust no-action letter to the Attorney General's office. The requesting party is under an affirmative obligation to make full, true, and accurate disclosure with respect to activities for which the antitrust no-action letter is requested. Each request must be accompanied by all relevant material information; relevant data; complete copies of all operative documents; the provisions of law under which the request arises; and detailed statements of all collateral oral understandings, if any. All parties requesting the letter must provide the Attorney General's office with whatever additional information or documents the office requests.

The Attorney General's office may seek whatever documentation, data or other material it deems necessary from the Agency for Health Care Administration, the State Center for Health Statistics, and the Department of Insurance. The Agency for Health Care Administration is to collect, coordinate, and analyze health care data and the Department of Insurance is to make available any relevant information on entities regulated by the Department of Insurance.

Within 90 days after it receives all information necessary to complete the review, the Attorney General's office must act on the no-action letter request. Upon review of the proposal, the Attorney General's office may either issue an antitrust no-action letter, decline to issue any type of letter, or take other appropriate action.

If an antitrust no-action letter is issued, the recipient must annually file with the Attorney General's office an affidavit stating that there has been no change in the facts presented, at which time the Attorney General's office is stopped from bringing an antitrust action concerning any specific conduct that is the subject of the no-action letter, as long as there is no change in any material fact. The no-action letter is, if relevant, admissible as evidence in any court proceeding in Florida. The Attorney General's office may bring any other action or proceeding based on a different set of facts."[10]

As set forth in s. 408.185, F.S., information submitted for review of antitrust issues is held confidential. The following information held by the Office of the Attorney General, which is submitted by a member of the health care community pursuant to a request for an antitrust no-action letter shall be confidential and exempt from the provisions of s. 119.07(1), F.S., and s. 24(a), Art. I of the State Constitution for 1 year after the date of submission.

[10] The Florida Senate, Interim Project Report 2001-044 " Public Records Exemption-Health Care Provider Information for Antitrust Review."

Documents that reveal trade secrets as defined in s. 688.002, F.S., which states that “trade secret” means information, including a formula, pattern, compilation, program, device, method, technique, or process that:

(a) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use; and
(b) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

Other types of information held confidential is preferred provider organization contracts, health maintenance organization contracts, and documents that reveal a health care provider's marketing plan.

In addition, proprietary confidential business information as defined in s. 364.183(3), F.S., which states, the term “proprietary confidential business information” means information, regardless of form or characteristics, which is owned or controlled by the person or company, is intended to be and is treated by the person or company as private in that the disclosure of the information would cause harm to the ratepayers or the person’s or company’s business operations, and has not been disclosed unless disclosed pursuant to a statutory provision, an order of a court or administrative body, or private agreement that provides that the information will not be released to the public. The term includes, but is not limited to:

- Trade secrets;
- Internal auditing controls and reports of internal auditors;
- Security measures, systems, or procedures;
- Information concerning bids or other contractual data, the disclosure of which would impair the efforts of the company or its affiliates to contract for goods or services on favorable terms;
- Information relating to competitive interests, the disclosure of which would impair the competitive business of the provider of information;
- Employee **personnel information unrelated to compensation, duties, qualifications, or responsibilities.**

Review of The Patient Self-Referral Act of 1992

Section 456.053, F.S., short-titled the “Patient Self-Referral Act of 1992,” was created to address issues involved in the referral of a patient by a health care provider for a service or treatment when the health care provider has a financial interest in the service or treatment. The statute prohibits any health care provider from referring a patient for the provision of a designated health service to an entity in which the health care provider is an investor. A designated health

service is defined as a clinical laboratory service, a physical therapy service, a comprehensive rehabilitation service, a diagnostic imaging service, or certain radiation therapy services.

In addition, health care providers are prevented from referring a patient for any service or item in which the health care provider is an investor, unless, pursuant to s. 456.053(5)(b), F.S., the investment interest is in registered securities issued by a publicly held corporation of a specified size; or if no more than 50 percent of the value of the investment interests are held by investors who are in a position to make referrals, and the terms under which the investment interest is offered meet specified conditions.

“Investment interest" is defined in s. 456.503(3)(k), F.S. as meaning an equity or debt security issued by an entity, including, without limitation, shares of stock in a corporation, units or other interests in a partnership, bonds, debentures, notes, or other equity interests or debt instruments. The following investment interests shall be excepted from this definition:

- An investment interest in an entity that is the sole provider of designated health services in a rural area;
- An investment interest in notes, bonds, debentures, or other debt instruments issued by an entity which provides designated health services, as an integral part of a plan by such entity to acquire such investor’s equity investment interest in the entity, provided that the interest rate is consistent with fair market value, and that the maturity date of the notes, bonds, debentures, or other debt instruments issued by the entity to the investor is not later than October 1, 1996;
- An investment interest in real property resulting in a landlord-tenant relationship between the health care provider and the entity in which the equity interest is held, unless the rent is determined, in whole or in part, by the business volume or profitability of the tenant or exceeds fair market value; or
- An investment interest in an entity, which owns or leases and operates a hospital licensed under chapter 395 or a nursing home facility licensed under chapter 400.

Section 456.053(3)(l), F.S., continues to define “Investor” to mean a person or entity who owns a legal or beneficial ownership or investment interest, directly or indirectly, including, without limitation, through an immediate family member, trust, or another entity related to the investor within the meaning of 42 C.F.R. s. 413.17,F.S., in an entity.

A “referral” is defined as the:

- Forwarding of a patient by a health care provider to another health care provider or to an entity which provides or supplies designated health services or any other health care item or service; or
- Request or establishment of a plan of care by a health care provider, which includes the provision of designated health services or other health care item or service.

Pursuant to s. 456.053(3)(0)3., F.S., certain types of orders, recommendations, or plans of care shall not constitute a referral by a health care provider and are therefore permitted or exempted from the limitations on referrals:

- Radiologist for diagnostic-imaging services;
- Physician specializing in the provision of radiation therapy services for such services;
- Medical oncologist for drugs and solutions to be prepared and administered intravenously to such oncologist’s patient, as well as for the supplies and equipment used in connection therewith to treat such patient for cancer and the complications thereof;
- Cardiologist for cardiac catheterization services;
- Pathologist for diagnostic clinical laboratory tests and pathological examination services, if furnished by or under the supervision of such pathologist pursuant to a consultation requested by another physician;
- Health care provider who is the sole provider or member of a group practice for designated health services or other health care items or services that are prescribed or provided solely for such referring health care provider’s or group practice’s own patients, and that are provided or performed by or under the direct supervision of such referring health care provider or group practice; provided, however, that effective July 1, 1999, a physician licensed pursuant to chapter 458, chapter 459, chapter 460, or chapter 461 may refer a patient to a sole provider or group practice for diagnostic imaging services, excluding radiation therapy services, for which the sole provider or group practice billed both the technical and the professional fee for or on behalf of the patient, if the referring physician has no investment interest in the practice. The diagnostic imaging service referred to a group practice or sole provider must be a diagnostic imaging service normally provided within the scope of practice to the patients of the group practice or sole provider. The group practice or sole provider may accept no more that 15 percent of their patients receiving diagnostic imaging services from outside referrals, excluding radiation therapy services;
- Health care provider for services provided by an ambulatory surgical center licensed under chapter 395;
- **Health care provider for diagnostic clinical laboratory services where such services are directly related to renal dialysis;**

- Urologist for lithotripsy services;
- Dentist for dental services performed by an employee of or health care provider who is an independent contractor with the dentist or group practice of which the dentist is a member;
- Physician for infusion therapy services to a patient of that physician or a member of that physician's, group practice; and
- **Nephrologist for renal dialysis services and supplies.**

Under the current exception, s. 456.053(3)(o)3.h., F.S., a nephrologist apparently would not be in violation of the Patient Self-Referral Act if she or he were to refer such patients to an entity he has a financial relationship for renal dialysis services or if he were to refer a patient for laboratory service in which he has a financial investment interest.

Prosecuting Violations of the "Patient Self-Referral Act of 1992"

Staff contacted ACHA and the Board of Medicine regarding the current remedies in place for violations of the Patient Self-Referral Act, s. 456.053, F.S., and the historical data regarding any disciplinary action taken for violations of such Act. The Patient Self-Referral Act affects seven regulated health care practices:

- Medicine
- Osteopathic Medicine
- Podiatry
- Optometry
- Dentistry
- Chiropractic
- Pharmacy

AHCA reports that the current data system does not allow them to identify specific cases involving violations of the Patient Self-Referral Act. According to AHCA staff, none of the licensing boards has imposed discipline for a violation of the Patient Self-Referral Act. However, boards do take action for similar type offenses. For example, during the past nine years, the Board of Medicine filed final disciplinary orders on seven physicians for kickback/split-fee violations of s. 458.331(1)(i), F.S. The following penalties were imposed in those cases:

- 2 Practitioners received voluntary relinquishment;
- 1 Practitioner received probation & fined;
- 1 Practitioner received Community service, reprimand, and was fined;
- 1 Practitioner received community service and was fined;
- 1 Practitioner received a fine, and was ordered additional continuing education; and
- 1 Practitioner was dismissed after formal hearing.

Typically, a complaint alleging a violation of the Patient Self-Referral Act, or any other violation of a practice act, is submitted by telephone or mail to AHCA's consumer services office in Tallahassee.

All complaints are considered confidential unless or until probable cause is found by the licensing board's probable cause panel. AHCA's staff at one of the 11 regional offices investigates legally sufficient complaints. Formal investigative reports, including records obtained by subpoena and any response or material provided by the subject licensee, are then reviewed by the Office of the General Counsel, Practitioner Regulation. This legal evaluation includes expert review for patient complaints.

The completed investigation and a draft Agency recommendation for each case are submitted to the licensing board's probable cause panel. The panel determines whether each complaint is resolved by an Administrative Complaint, a Letter of Guidance, or Dismissal. Cases resulting in an Administrative Complaints become matters of public record 10 days thereafter. Other resolutions remain confidential. Licensees with Administrative Complaints are subject to discipline ranging from fines and costs to revocation. Licensees who dispute material issues of fact may elect a formal hearing before an Administrative Law Judge of the Division of Administrative Hearings.

Regardless of whether there is a formal hearing or the case goes directly to the licensing board, the final decision on whether a violation is proven and what penalty, if any, is appropriate, is made by the licensing board based upon the merits of each case and the board's published disciplinary guidelines for each offense.

Last fiscal year, health care probable cause panels directed the filing of about 2,000 Administrative Complaints and health care licensing boards took disciplinary action in about 2,000 cases.

RECOMMENDATIONS

Staff has reviewed and analyzed the kidney dialysis studies conducted in 1999 and 2000 and identified the deficiencies of those studies, determined the impact of repealing exemptions contained in the Patient Self-Referral Act of 1992, investigated the claims of fraud and abuse in the Medicaid industry, studied provisions relating to Antitrust violations, and examined the feasibility of divestiture of services, and have concluded the following:

Patient Self-Referral Act

When the Patient-Self Referral Act was statutorily created in 1992, most nephrologists treated their patients with end stage renal disease on an outpatient basis in an independent clinic that was typically owned by the nephrologist. The Act, as set forth in s. 456.053, F.S., governs physician practice and within the confines of this report, speaks to either a nephrologist or a pathologist. When a violation occurs within s. 456.053, F.S., the violation is prosecuted by ACHA through the disciplinary panel of the Board of Medicine. If the exemptions in ss. 456.053(3)(o)3.h. and 456.053(3)(o)3.l., F.S., were to be repealed and it becomes illegal for a nephrologist to refer his patients to a clinic in which he has a financial interest, and he is subsequently prosecuted to the fullest extent by the Board of Medicine, the physician's license would possibly be suspended and he could face fines and penalties up to $100,000.

Removing qualified physicians from practicing medicine, will not address the concerns raised---which are primarily increased competition among corporations, prevent over-utilization, and promote better patient care. However, if a practicing nephrologist is prohibited from referring a patient to a facility for whom he is employed, such as the relationship that currently exist when the physician is the medical director of an outpatient clinic or hospital, it may impede the dialysis clinic from employing a physician from their local community for service. As well, it may require the dialysis clinic to employ a physician that is not treating patients as the medical director of the facility.

Fraud and Abuse

Both the Medicare and Medicaid programs are highly regulated by the state and federal governments as demonstrated in this report. In the event there is fraud and abuse within a practicing facility, there are clear and defined remedies to investigate, fine and prosecute such abuse as demonstrated by the Operation Restore Trust Project by the federal government's office of Program Integrity for Medicare and Medicaid.

In 1995, the Legislature amended s. 409.905, F.S., Mandatory Medicaid Services, to include the treatment for ESRD services. According to AHCA, there are about 400+ Medicaid funded Florida ESRD patients out of approximately

17,000+ total ESRD patients in Florida. In fiscal year 1999-2000, Florida spent approximately $113,000,000 in Medicaid dollars to treat patients diagnosed with end stage renal disease. The $113,000,000 represents all costs associated with treatment, hospitalization, transportation, clinical laboratory charges and pharmaceuticals. Of that amount, only $4-5 million was spent on actual charges for clinical dialysis services and laboratory cost.

Enforcing the regulations that exist through ACHA is a clearer and more definitive avenue to address any concerns of fraud and abuse than creating additional programs or government authority as recommended in the USF Report.

Antitrust Violations

In the event it is suspected that a monopoly exists within the health care industry, there are clear and definitive remedies under the Attorney General's office through the enforcement of the antitrust statutes. When the Attorney General's office investigates an industry for a monopoly and there is found no cause for concern, no legal action is taken and therefore this information is considered confidential and is not publicly disclosed. If such an investigation has occurred within Florida, the Attorney General's office is not at liberty to disclose such an investigation. However, through the no-action antitrust statues, an industry may ask the Attorney General's office to issue an opinion as to whether a monopoly exists, which is made public.

Feasibility of divestiture of clinical laboratory and clinical dialysis services

Currently, clinical dialysis facilities operate in tandem with their corresponding laboratory. A patient that is treated in a Gambro, Fresenius or DaVita clinic has the blood work sent directly from the clinic to the laboratory. All patient registration/financial information and medical records are obtained on the clinical side. In order to bill for laboratory work done on the patient specimen, the laboratory is dependent on the clinic to provide all patient financial information.

The selection of the use of a laboratory, absent any third party payor restrictions, has historically been at the discretion of the physician or facility providing the service. The decision is based on the reliability of service that the lab provides, and this decision is considered an important decision-making process in overall patient care. Only when there is substantial risk to patient care should the state intervene in making medical decisions concerning the delivery of patient care. The divestiture of such services, absent any direct risk to patient care, is not recommended.

In conclusion, there is convincing evidence that mechanisms are already in place to address allegations of fraud and abuse in the Medicaid industry without creating additional programs or government authority. Additionally, regulations already exist to address concerns of Antitrust

violations. Further, it is concluded that repealing the nephrologist's exemptions in the Patient Self-Referral Act will not increase competition or provide opportunities for competition, but instead would eliminate provisions that are obsolete in today's renal dialysis market.

It is therefore recommended that no legislative action is needed to address the concerns regarding monopoly, over-utilization of services to patients with ESRD, or the divestiture of vertically integrated services within the ESRD industry.

Additionally, it is recommended that through the Florida Health Care Community Antitrust Guidance Act, codified at s. 408.18, F.S., under the investigation of the Attorney General's office that one or all four major corporations seek guidance from the Attorney General's office for a public determination as to whether a monopoly exists in the dialysis industry.

Appendix Index

Letter from Representative Frank Farkas, D.C., Chair, Health Regulation Committee, to Laura Branker, Acting Secretary, Agency for Health Care Administration, initiating the Interim Project, dated July 23, 2001.

Letter from Rufus Nobel, Inspector General, Agency for Health Care Administration, responding to concerns of fraud or abuse within the Florida Medicaid program, dated October 18, 2001.

Attorney General's staff response regarding procedure for investigation of antitrust violations, dated October 16, 2001.

Gambro Healthcare Patient Services, Inc., vs. Mark Ginsburg; et al, Fla. 17th Cir. Ct., Case No. 97009044, June 13, 1997.

Mark Ginsburg; et al. vs. Bernard Pachter; et al. vs. Arthur Rosenthal; et al, Fla. 17th Cir. Ct., Case No. 99-08930 CACE (18), May 10, 2000.

Mark Ginsburg, M.D.; et al vs. Gambro AB and COBE Laboratories, Inc., Fla. 17th Cir. Ct., Case No. 97-018445 CA (13).

Corporate Integrity Agreement Between the Office of the Inspector General of the Department of Health and Human Services and Gambro Healthcare Laboratories Services, Inc., July 3, 2000.

Corporate Integrity Agreement Between the Office of the Inspector General of the Department of Health and Human Services and Fresenius Medical Care Holdings, Inc., January 18, 2000.

Draft Report of the 1999 AHCA Study, Laboratory Services for Dialysis Patients in Florida, December 1999.

Final AHCA Report, Laboratory Services for Dialysis Patients in Florida, February 2000.

AHCA response regarding number of Medicaid ESRD beneficiaries, Program Integrity Investigations, payments for ESRD services, August 13, 2001.

Letter from Department of Health & Human Services, Centers for Medicare and Medicaid Services to Committee on Health Regulation, October 15, 2001.

Stark Amendment (Federal Regulations), US Code: Title 42, Section 1395nn, as of 1/5/99.